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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,849	01/30/2002	Stephen Mark McAllister	P51223	9605

7590 06/24/2008
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Corporate Intellectual Property - UW2220
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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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06/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33, 35, 38-40, 71-97 and 112-134 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While the present specification at page 28 discloses dissolution modifying excipients can be mixtures with each other, it appears that nowhere in the present specification provides support for newly added limitations "first and second dissolution modifying excipients". The present specification does not appear to provide support that the first dissolution modifying excipient must be a swellable solid as required in claim 11, nor the specification provides support for the limitations that require the second dissolution modifying excipient must be lactose, sodium starch glycollate, croscarmellose sodium copovidone, crospovidone, polyvinyl pyrrolidone, disintegrant, or wicking agent, as well as the more specific combinations recite in claims 114-134.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 19, 31, 35, 72, 86 and 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15, 19, 86 and 89 recite the limitation "the dissolution modifying excipient" in line 2, it is unclear whether this limitation is referring to the "first", "second" or both of the dissolution modifying agents in claim 1.

Claim 31 is rejected for failing to further limit the subject matter of claim 1. While claim 1 requires the present of lubricant, claim 31 omits lubricant in some of the combinations. See for example all the combinations in page 11 of the amended claims filed 03/20/08. The amount of stearyl alcohol (lubricant) is 5%, which is outside of the range of lubricant recites in claim 1 (10-30%). Further, the amendment has the status of claim 31 as "previously presented", this appears to be incorrect.

Claim 31 recites the limitation "low substituted hydroxypropyl cellulose" in page 10 of the amended claims filed 03/20/08. There is insufficient antecedent basis for this limitation in the claim. Is this supposed to be either the first or second dissolution modifying excipient? No support can be found.

Claim 35 is rejected for failing to further limit the subject matter of claim 1. Formulation 7, in claim 35 contains 5% stearyl alcohol, which is outside the lubricant range of about 10% to about 30% recites in claim 1. Further, the amount of stearyl alcohol in formulation 11 is misplaced.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

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the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" or "example" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 35 and 72 recite the broad recitation "capsule shell composition according to Claim 1", and the claim also recites "example" of formulations with specific amounts and combinations which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The 102(e) rejection has been withdrawn in view of applicant's amendment and arguments.

Claim Rejections - 35 USC § 103

The 103(a) rejections of record (office action dated 09/20/07) are maintained for the reasons below.

Response to Arguments

Applicant's arguments filed 03/20/08 have been fully considered but they are not persuasive.

Applicant argues that the Examiner is picking and choosing from a long list of "other polymers" with no particular direction to pick and choose HPC.

However, in response to applicant's arguments, HPC is not recited in the independent claims.

Applicant argues that Petereit does not anticipate a combination of a first and second dissolution modifying excipients.

However, it is noted that the first and second dissolution modifying excipients can be the same. This is evident by the present claims, see for example, claims 14 and 16.

Applicant argues that Petereit teaches the use of stearyl alcohol as a lubricant, but this is out of a long listing.

However, it is noted that stearyl alcohol is not recited in the independent claims.

Applicant argues that the failure of Petereit is not remedied by the teachings of the secondary references. There is no motivation to take the primary reference and modify it by the teachings of the secondary references since they are not concerned with the same teachings. Accordingly, the combination of references does not teach or suggest all the elements of the claimed invention. Further, the PTO has not satisfied any of the necessary requirements to maintain a prima facie obviousness rejection over the claims herein.

However, In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present case: Hatano is relied upon solely for the teaching of excipients such as lactose in a capsule shell is known in the art. The Handbook of Pharmaceutical Excipients is cited for the teaching of using lubricant and surfactant in a capsule shell is also known. The rejection over Adams is maintained because the capsule shell of the present invention does not exclude the enteric coating layer which contains about 5% to about 50% stearyl alcohol as taught by Adams.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618